



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/649,077 | 08/27/2003 | Birinder R. Boveja | | 4660 |

43987 7590 11/01/2006

BIRINDER R. BOVEJA & ANGELY WIDHANY
P. O. BOX 210095
MILWAUKEE, WI 53221

EXAMINER

BERTRAM, ERIC D

ART UNIT PAPER NUMBER

3766

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,077

Applicant(s)

BOVEJA ET AL.

Examiner

Eric D. Bertram

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) 25-37 and 49-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/24/06 regarding the 35 USC 102(b) rejection of claims 15-19, 21-23, 47 and 48 have been fully considered but they are not persuasive.

The applicant submitted that item 33 in Adkins is a voltage regulator, and not an implanted pulse generator module. However, Adkins clearly describes how the regulated voltage from item 33 is supplied to the logic and control section 35 to control the characteristics of the output pulses (Col. 2, lines 32-40). Therefore, the voltage regulator 33 and the logic and control section 35 act as an implanted pulse generator module inside of implanted stimulator 25.

2. The applicant further argues that item 40 is a built in antenna for changing programs, and not an implanted stimulus-receiver for providing pulses to tissues with an external stimulator. However, independent claims 15 and 47 do not require the external stimulator to provide pulses to tissues. Claims 15 and 47 recite "providing electrical pulses from **either** said implanted pulse generator module **or** external stimulator." As described above, since implanted stimulator 25 delivers electrical pulses, the limitations of the claim are met. Finally, as stated by the applicant, item 40 is indeed an antenna for changing programs. Since the programs contain the desired parameters of stimuli, and antenna 40 inductively receives these programs and is implanted in the body, antenna 40 clearly acts as an implanted stimulus-receiver module. Therefore, the logic and control section 35 selectively operates the implanted pulse generator module 33, 35

Art Unit: 3766

to deliver pulses, as well as the implanted stimulus-receiver module 40 to receive programs.

3. The applicant also contends that item 18 is a programming wand, and not an external stimulator. As stated above, independent claims 15 and 47 do not require that the external stimulator deliver pulses. As a result, since the programming wand 18, in conjunction with computer 20, delivers stimulus parameters from outside the body to the implanted stimulus-receiver module 40, programming wand 18 is considered to be an external stimulator, as claimed by the applicant. Furthermore, implanted stimulus-receiver 40, external stimulator 18, and computer 20 form a network, since the broadest reasonable interpretation of a network is a group (two or more) of devices that communicate back and forth using a set of protocols. In this case, there are three devices using inductive signals for use in bidirectional communication (Col. 2, lines 53-61).

4. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the system can switch between two modes of stimulation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. Applicant's arguments regarding the 35 USC 103(a) rejection of claim 24 has been fully considered but they are not persuasive. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which

Art Unit: 3766

he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. In response to the rejection, the applicant vaguely stated that the Mann reference leads in a direction different from the direction of the claimed invention. Since the applicant went into no further detail as to how Mann leads in a different direction, the rejection is still deemed to be proper

6. Applicant's arguments with respect to claims 1-14 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on 5/4/06 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

8. Claims 25-37 and 49-57 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

9. The amendments to overcome the 112(2) rejections of claims 1-24, 47 and 48 are acknowledged and accepted. As a result, the 35 USC 112(2) rejections of claims 1-24, 47 and 48 are withdrawn.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3766

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al. (US 5,188,104, hereinafter Wernicke). Wernicke discloses a method for stimulating and neuromodulating the vagus nerve of a patient in order to provide treatment for eating disorders (see abstract). Wernicke provides an implanted stimulator 10 with an implanted pulse generator module 36, and an implanted stimulus-receiver module 60. Wernicke further provides an external stimulator 47 that is inductively coupled to the implanted stimulus receiver 60, as shown by the inductor symbol 60 in figure 2. The external stimulator 47 is thus wirelessly networked for bi-directional communications with the implanted stimulator in order to manage and optimize the patient's therapy, specifically the pulse parameters, including current, pulse frequency, pulse width, amplitude and on-off timing (Col. 11, lines 23-28 and Col. 9, lines 41-56). Wernicke also provides an implanted lead 20 in electrical contact with the implanted stimulator, as well as an electrode array 40 in contact with the vagus nerve below a diaphragmatic level, as shown in figure 2 (Col. 10, lines 1-11). The implanted stimulator further comprises controlling means in the form of microprocessor 27 that controls both the implanted pulse generator and the implanted stimulus receiver (Col. 9, lines 10-18). Wernicke further states that a magnet is used to activate the system, i.e. program the system to an "on" state (Col. 10, lines 11-20).

12. Claims 15-23, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Adkins et al. (US 5,928,272, hereinafter Adkins). Adkins discloses a

Art Unit: 3766

method for stimulating and neuromodulating the vagus nerve of a patient in order to provide treatment for neurological disorders (see abstract). Adkins provides an implanted stimulator 25 with an implanted pulse generator module 33, 35, and an implanted stimulus-receiver module 40. Adkins further provides an external stimulator 18 that is inductively coupled to the implanted stimulus receiver 40, as shown by the inductor symbol 40 in figure 2. The external stimulator 18 is thus wirelessly networked for bi-directional communications with the implanted stimulator in order to manage and optimize the patient's therapy, specifically the pulse parameters, including current, pulse frequency, pulse width, amplitude and on-off timing (Col. 2, lines 35-40 and 52-60). Adkins also provides an implanted lead 16 in electrical contact with the implanted stimulator, as well as an electrode array 15 in contact with the vagus nerve above a diaphragmatic level, as shown in figure 1 (Co. 1, lines 55-60). The implanted stimulator further comprises controlling means in the form of microprocessor 36 that controls both the implanted pulse generator and the implanted stimulus receiver (Col. 2, line 35). Adkins further states that a magnet is used to activate the system, i.e. program the system to an "on" state (Col. 2, lines 48-52).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3766

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke in view of Adkins. Wernicke, as described above, discloses the applicant's basic invention including applying electrical pulses to the vagus nerve to treat eating disorders, which is a neurological issue. However, Wernicke does not disclose providing electrical pulses to the vagus nerves at a level above the diaphragmatic level. Attention is directed to the secondary reference of Adkins, which discloses a method for stimulating the vagus nerve to treat neurological disorders at a level above the diaphragmatic level, as shown in figure 1. Therefore, it would have been obvious to one

Art Unit: 3766

of ordinary skill in the art to modify the method of Wernicke by stimulating the vagus nerve to treat neurological disorders at a level above the diaphragmatic level as taught by Adkins since this is a known technique for stimulating the vagus nerve to treat a neurological disorder.

17. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke in view of Barrett et al. (US 2002/0087192, hereinafter Barrett). Wernicke, as described above, discloses the applicant's basic invention with the exception of stimulating both the left and right vagus nerves in order to treat eating disorders.

Attention is directed to the secondary reference of Barrett, that discloses stimulating the left and right vagus nerves, using one or two stimulators, in order to treat obesity (see abstract and figures 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Wernicke to stimulate both the left and right vagus nerves below the diaphragm since this is a known method that may be more easily accomplished than stimulation above the diaphragm (para. 0015).

18. Claims 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke in view of Mann et al. (US 2002/0055761, hereinafter Mann). Wernicke, as described above, discloses the applicant's basic invention with the exception of using a rechargeable battery in the implanted stimulator capable of being recharged by an external power source. Attention is directed to the secondary reference of Mann, that discloses the use of an external power source 92 use to recharge a battery 15 that is in implanted stimulator 100. Therefore, it would have been obvious to one of ordinary skill

Art Unit: 3766

in the art at the time of the applicant's invention to modify the system of Wernicke by adding an external power source to recharge a battery since this allows the power to be replenished without removing the implanted stimulator from the patient.

19. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adkins in view of Mann et al. (US 2002/0055761, hereinafter Mann). Adkins, as described above, discloses the applicant's basic invention with the exception of programming the implanted stimulator with a magnet. Attention is directed to the secondary reference of Mann, that discloses the use of a magnet in an external programmer 20, used to program an implanted stimulator 10. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Adkins by adding a magnet as a programmer since this is an old and well known method, as taught by Mann.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3766

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1, 15 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10/196,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe the same general invention for stimulating a vagus nerve to treat neurological disorders.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-24, 47 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-42, 48, 51, 53-55 and 62 of U.S. Patent No. 6,611,715. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe the same general invention for stimulating a vagus nerve to treat neurological disorders.

Conclusion

23. Due to the addition of the Double Patenting Rejections, this action is made NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

Art Unit: 3766

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB